

Mr. GUTKNECHT. Mr. Speaker, I will attempt to read from an e-mail which was sent from a young ensign aboard the U.S.S. *Winston Churchill* to his parents. The *Churchill* is an *Arleigh Burke*-class AEGIS guided-missile destroyer, commissioned March 10, 2001, and is the only active U.S. Navy warship named after a foreign national.

I read: "Dear Dad: We are still at sea. The remainder of our port visits have all been canceled. We have spent every day since the attacks going back and forth within imaginary boxes drawn in the ocean, standing high-security watches and trying to make the best of it. We have seen the articles and the photographs, and they are sickening. Being isolated, I do not think we appreciate the full scope of what is happening back home, but we are definitely feeling the effects.

"About 2 hours ago, we were hailed by a German Navy destroyer, *Lutjens*, requesting permission to pass close by our port side. Strange, since we were in the middle of an empty ocean, but the captain acquiesced and we prepared to render them honors from our bridge wing. As they were making their approach, our conning officer used binoculars and announced that the *Lutjens* was flying not the German but the American flag. As she came alongside us, we saw the American flag flying at half mast and her entire crew topside standing at silent, rigid attention in their dress uniforms.

"They had made a sign that was displayed on her side that read "We Stand by You." There was not a dry eye on the bridge as we stayed alongside for a few minutes and saluted. It was the most powerful thing I have seen in my life. The German Navy did an incredible thing for this crew, and it has truly been the highest point in the days since the attacks. It is amazing to think that only a half-century ago things were quite different.

"After *Lutjens* pulled away, the officer of the deck, who had been planning to get out later this year, turned to me and said, 'I'm staying Navy.'"

Mr. Speaker, to our German friends we can only say, *danke schoen*. To our countrymen and colleagues I say, be of strong heart, we are not alone. We will prevail.

Mr. Speaker, before I yield back, a number of colleagues have asked if they could get copies of this e-mail as well as photos of the Navy destroyer *Lutjens*. They can get that by simply going to my Web address at gil.house.gov.

PEDIATRIC EXCLUSIVITY BILL

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Michigan (Mr. STUPAK) is recognized for 5 minutes.

Mr. STUPAK. Mr. Speaker, I rise today to speak on a bill that will be

coming to the floor soon. H.R. 2887 is commonly called the pediatric exclusivity bill. This was a good bill. It was passed and implemented back in 1997. It had a 5-year sunset, so it is necessary for Congress to reauthorize the pediatric exclusivity bill.

Pediatric exclusivity simply says this: If a drug company that currently has a drug on the market will do an exclusive study for young people, those 18 or under, we will grant to them a patent extension for 6 years.

It is amazing, but as drug companies put forth drugs, they were not required to see what the effect would be on young people. Thus, we created the pediatric exclusivity bill to make sure an opportunity was provided to have studies done to make sure the proper dosage, the amount and the type of drug, would be beneficial to young people, those under 18 years of age. Just for agreeing to do a study that the FDA wants for young people, a drug company can get its patent extended. That is of great benefit to the drug company, of course, because they hold the patent and make money off the drug, and this bill is now due to be reauthorized.

As we move through this bill in our Subcommittee on Health of the Committee on Energy and Commerce, there are a number of improvements we would like to see made with the bill. While there have been a number of improvements made already, there is still one part of the bill that troubles me, and hopefully, I will be able to offer an amendment to correct this inequity in the bill. What my amendment would say is that if we provide a pediatric exclusivity, before that patent extension is provided, the drug company must make the necessary label changes on a product that has been studied.

In fact, I would like to quote the FDA's report to the Congress dated January of this year. It says, and I quote, "The ultimate goal of encouraging pediatric studies is to provide needed dosing and safety information to the physicians in product labeling." To paraphrase, and I want to emphasize, "The goal of pediatric exclusivity is the labeling." It is the labeling where we find out how much to give, the safety information, and who should be given it. That is why I must offer my amendment when this bill comes to the floor. My amendment would tie the grant of exclusivity to the necessary labeling changes.

There have been 33 drugs approved for pediatric exclusivity, but only 20 of them have made the needed changes on the label. How would a doctor, a parent, or a patient who is under 18 know what is the right dosage or if this drug is safe for them without this information? Currently, the exclusivity period is given only for conducting studies. For the safety of our children, for our health care system, this must and should be changed.

Take, for example, one of the drugs that has been granted pediatric exclusivity, Eli Lilly's drug Prozac. The benefit to the public, specifically parents, patients and pediatricians, is zero, because the manufacturer has yet to place any information in the public record regarding the pediatric dosing or other data relating to the drug's safety in juvenile populations. Just for doing a study, for doing very little to aid our understanding of the operation of this antidepressant drug, they are allowed to have the pediatric exclusivity, to make the money, but not without giving us full disclosure of the needed safety information. That information on Prozac is never given to doctors, parents and patients on how it affects young people.

Sadly, physicians and parents have no way of knowing what the results of the study were on Prozac regarding the myriad of presumed uses of Prozac in young people. Unless Eli Lilly elects to tell us, we do not know what testing occurred, in what specific age groups, what dosage, or what reactions. Pediatricians, parents, and patients have no information; they are literally left in the dark.

When the current bill comes to the floor, it will only require that manufacturers in the future will be required to label their products after the results are known. But that knowledge will not be given until 11 months after the product is on the market. That gives them 11 months to negotiate with the FDA in a secret proceeding, unless the FDA is prepared to declare a product misbrand, and the FDA has been reluctant to do so.

Under my labeling amendment, which I hope to bring to the floor, all new drugs must complete the labeling requirement before the product is marketed. I cannot understand why we allow drug manufacturers to undertake a pediatric study but not provide the doctors, the patients, and the parents with the results of this study and the information they need to make it available.

FOOLISHNESS OF FIAT

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Texas (Mr. PAUL) is recognized for 5 minutes.

Mr. PAUL. Mr. Speaker, the world's politicians, special interests, government bureaucrats, and financiers all love fiat money because they all benefit from it. But freedom-loving, hard-working, ethical and thrifty individuals suffer.

Fiat money is paper money that gets its value from a government edict and compulsory legal tender laws. Honest money, something of real value, like a precious metal, gets its value from the market and through voluntary exchange. The world today is awash in